

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N-0424]

Mohammad Uddin; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Mohammad Uddin from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Uddin was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Uddin failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061 Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On November 19, 1993, the United States District Court for the District of Maryland entered judgment against Mr. Uddin for one count of obstruction of an agency proceeding, a Federal felony offense under 18 U.S.C. 1505.

DAB

Display Date	9/28/00
Publication Date	9/29/00
Certifier	Jan W. Wadsworth

As a result of this conviction, FDA published in the **Federal Register** of January 12, 1999 (64 FR 1809), a notice proposing to permanently debar Mr. Uddin from providing services in any capacity to a person that has an approved or pending drug product application and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Uddin was provided 30 days to file objections and request a hearing. Mr. Uddin did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

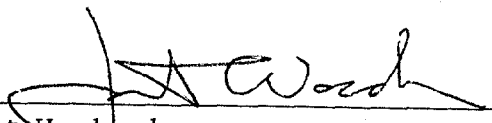
Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Mohammad Uddin has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Mohammad Uddin is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [*insert date of publication in the Federal Register*] (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Uddin, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Uddin, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Uddin during his period of debarment.

Any application by Mr. Uddin for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0424 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability

of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/11/00
September 11, 2000

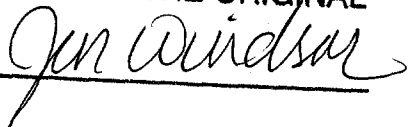


Janet Woodcock
Director,
Center for Drug Evaluation and Research

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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COPY OF THE ORIGINAL



Jen Windsor